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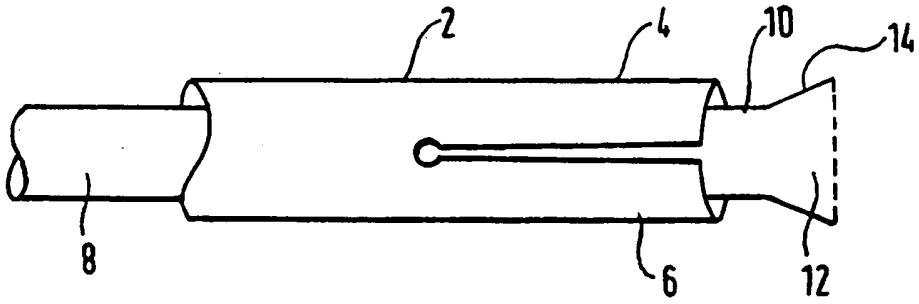

(57) Abstract

An apparatus is provided for removing blockages from fluid flow paths, such as arteries. The apparatus comprises a plurality of members (4, 6) which can be moved between a radially contracted state which corresponds to an inoperative state, and a radially expanded state where they bear against the wall of the fluid flow path and act to cleave the debris from the wall.

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APPARATUS FOR AND METHOD OF REMOVING A BLOCKAGE FROM BODY CHANNELS

The present invention relates to an apparatus for, and method of, removing a blockage from an elongate fluid flow path. Such a fluid flow path may be defined by a pipe or part of a animal or human circulatory system, such as an artery.

Atherosclerosis is a disease of the artery walls in which they thicken and lose their elasticity. As the artery walls thicken the blood flow through the artery becomes restricted and in severe cases the blood flow can be halted completely. The occlusion of the artery can be partial or total and the occlusions can be up to 700 mm in length.

Techniques for re-opening an artery are known. US5368603 describes an arrangement in which a hollow tube is passed into the artery. The tube has an open window and a axially moveable blade is located within the tube. The tube is pushed into the material occluding the artery and some of the material extends through the window. The blade is then moved axially with respect to the window so as to guillotine off some of the occluding material.

US4890611 describes an arrangement in which a guide wire is passed through the occluding material and then a corkscrew type arrangement is guided along the wire so as to break-up the material. US4621636 describes another arrangement in which a cutting device is guided via a guide wire which has been passed through the occluding material. Each of these arrangements assumes that it is possible to pass a guide wire through the occluding material or to deform it to an extent that a cutting device can be brought into contact with the material. It should be noted that the occluding material may include relatively hard objects, such as calcified elements which can deflect the path of a guide wire and cause it to puncture an arterial wall.

A further known technique for separating the occluding material from the arterial wall is endarterectomy. In this technique a ring stripper is surgically inserted into a diseased artery

and is moved along the length of the occlusion so as to separate the occluding material and diseased arterial tissue from the healthy arterial wall. The stripper, or a cutting head of a endarterectomy catheter is guided through the artery by means of a guide wire.

According to a first aspect of the present invention there is provided an apparatus for removing a blockage from an elongate fluid flow path defined by a surface or wall, comprising separating means for separating the material forming the blockage from the surface or wall.

It is thus possible to provide an apparatus which can be inserted into a fluid flow path, such as an artery, and advanced along that path without the need for the prior inclusion of a guide wire. Thus the apparatus is suitable for opening fully occluded fluid flow paths. However, if a guide wire can be inserted, then the apparatus can guided along a previously passed guide wire.

Preferably the separation is achieved by exploiting a cleavage plane occurring at or adjacent an interface between the material and the surface or wall. The surface or wall may be a tissue wall, such as an arterial wall, and the blockage may partially or fully occlude the artery. The blockage may comprise cholesterol crystals, calcified deposits, fibrous material, plaque and necrotic cell debris and may include elements of the arterial wall. The arterial wall consists of 3 circumferential layers known as tunicae. The formation of a blockage can damage the inner most layer of the arterial wall (the tunica intima) and in such circumstances the cleavage plane can lie within the tunica intima or between the tunica intima and the tunica media (the middle layer of the arterial wall) or within the inner layers of the media.

Preferably the separating means comprises at least one finger attached at or adjacent a first end of a first flexible member. Advantageously the first flexible member is in the form of a hollow pipe.

Preferably the or each finger is moveable between an inoperative position, at which the axis or axes are substantially parallel to one another and/or parallel to a longitudinal axis of

an end portion of the flexible member, and an operative position such that the fingers are inclined with respect to one another. Thus the fingers extend outwardly from the end of the flexible member to define part of a cone or other fluted shape when they are at their operable position.

Preferably finger operating means is provided to urge the or each finger to move between the operative and inoperative positions. Advantageously the fingers may be resiliently biased towards one or other of the operative and inoperative positions.

In use, the distal ends of the fingers are urged into contact with the surface or wall and act to separate the material of the blockage from the surface or wall. In the case of an artery, the arterial wall is more elastic than the material of the blockage and the fingers urge the arterial wall outwardly thereby expanding the artery and cleaving the blockage from the arterial wall.

In a first embodiment, the fingers are resiliently biased towards the inoperative position and an operating means is selectively urged into engagement with an inner surface of the fingers. The engagement results in a camming action which deforms the resilient material of the fingers and causes the distal ends of the fingers to be moved radially outwardly.

The camming action may be provided by forming the operating means as a frustro-conical element with the apex of the cone in communication with a further flexible element. The further flexible element may be in the form of a tube substantially coaxial with and contained within the first tube. Alternatively the operating means by be provided by an annular element moveable longitudinally so as to provide a camming action. As a further alternative, an annular balloon can be placed adjacent to the inner surface of the fingers and inflated in order to urge the fingers outwardly. A cylindrical support may be provided radially inwardly of the balloon to prevent it from sealing the end of the pipe.

As a further alternative, the fingers may be resiliently biased outwardly and an outer sheath may surround the first flexible member and be moveable longitudinally with respect thereto. Thus the sheath can be moved so as to cover the fingers, thereby moving them to

the inoperative position, and to undercover the fingers thereby moving them to the operative position. Advantageously the outer sheath is in the form of a flexible tube.

The or each finger may be formed as a linear element of constant width. Alternatively they may be enlarged at their distal ends. This has the advantage of increasing the area of contact with the wall or surface. This helps in uniformally stretching the arterial wall. Additionally or alternatively the fingers may be formed along a helical path.

Preferably the distal ends of the fingers are profiled so as to turn inwardly, thereby presenting a smooth surface to engage the surface or wall. This helps reduce damage to the surface, such as the arterial wall. The end of the finger may be profiled to have a cutting edge in a manner similar to that of a chisel so as to assist the cleaving action.

The sides of the fingers may further be profiled to assist in the cleaving action in the event that the first flexible member is rotated along its axis. Vibratory means may be provided so as to cause longitudinal and/or rotational vibration of the first member, and hence the fingers, in order to assist in the cleaving action. Alternatively or additionally gas (such as carbon dioxide) can be injected along the cleavage plane. This can be achieved by injecting the gas adjacent or intermediate the fingers, or by forming gas flow passages as part of the fingers thereby allowing gas to be injected from the ends of the fingers.

Preferably the apparatus further comprises a removal means for disintegrating or capturing the material of the blockage. The removal means may comprise a drill, or a griding element, or an ultrasonic element, or an other suitable pulverising or fracturing element for breaking up the material of the blockage. The material of the blockage can then be sucked up a discharge pipe in order to remove it. As a further alternative, laser devices may also be used to disintegrate the blockage. Laser light can be directed along an optical fibre or along a column of fluid contained within the apparatus. The fluid could be an irrigation fluid used within the catheter.

In yet a further alternative embodiment, the blockage may be captured inside the first flexible member when the member is in the form of a pipe and be removed from the fluid

flow path by virtue of removal of the apparatus. Thus the action is similar to that of a core sampler.

An enlarged version of the apparatus may be used to unblock pipes or sewers. In this embodiment the pipe is relatively rigid but the material of the blockage will be relatively compressible thereby enabling the distal ends of the fingers to be forced between the material of the blockage and the pipe thereby cleaving the material from the pipe and enabling the material to be broken up by the removal means.

According to a second aspect of the present invention there is a provided a method of removing a blockage from an elongate fluid flow path defined by a surface or wall, comprising the step of separating the material forming the blockage from the surface or wall and the step of removing or disintegrating the material of the blockage.

It is thus possible to provide an apparatus, such an endarterectomy catheter for the removal of blockages.

The present invention will further be described, by way of example, with reference to the accompanying drawings, in which;

Figure 1 is a perspective view of an endarterectomy catheter consisting a first embodiment of the present invention in the inoperative state;

Figure 2 shows the catheter of Figure 1 in the operative state;

Figure 3 is a schematic cross section through a endarterectomy catheter consisting a second embodiment of the present invention;

Figure 4 is a perspective view of an endarterectomy catheter consisting a third embodiment of the present invention;

Figure 5 is a perspective view of a modification of the catheter shown in Figure 4;

Figure 6 is a plan view of a modified arm shape for use with anyone of the illustrated embodiments;

Figure 7 shows an arrangement of arms in the inoperative state for a catheter having an arm shape as shown in figure 6;

Figure 8 is a side view of an arm suitable for use in any of the preceding embodiments;

Figure 9 is a schematic cross-section through a catheter constituting a further embodiment of the present invention;

Figure 10 is a schematic cross-section through part of a catheter constituting another embodiment of the present invention; and

Figure 11 shows a variation on the embodiment shown in Figure 10.

The catheter shown in Figure 1 comprises a flexible plastic tube 2 formed from medical grade plastics. The tube 2 may have a PTFE coating in order to reduce friction between it and its surroundings. The tube 2 is sufficiently long to extend from a distal end (illustrated) which is inserted within a patient's artery to an operating position outside the patient's body. The distal end of the tube 2 has been modified by the inclusion of a plurality of slits in the plastic in order to form at least two fingers, of which only two fingers 4 and 6 are illustrated, at the distal end of the tube. A second tube 8 is arranged within the first tube and is longitudinally movable with respect thereto. The second tube is also sufficiently long to extend from the side of an arterial occlusion to a position outside the body. The distal end 10 of the second tube 8 terminates with a frustro-conical portion 12 so as to form a funnel. As illustrated in Figure 1, the end portion 12 of the second tube can be moved to a position where it does not engage the fingers 4 and 6 of the first tube. This corresponds to the non-operative state of the catheter. It is in this configuration that the catheter is inserted through an incision and into the blocked artery. The catheter can

then be pushed into the artery until such time as the distal end of the catheter is adjacent the arterial occlusion.

In order to operate the catheter, the second tube 8 is moved rearwardly with respect to the first tube 2 thereby causing an outer surface 14 of the conical element 12 to abut against an inner surface 16 of the fingers 4 and 6 thereby urging the fingers to flex outwardly, as shown in Figure 2. This action urges the ends 18 and 20 of the fingers 4 and 6 into engagement with the arterial wall (not shown) thereby causing the artery to become dilated. The artery is more elastic than the material blocking it and this property helps in the separation of the arterial wall from the blockage. The endarterectomy catheter is then moved forwards along the artery (ie. in the direction represented by arrow A) so as to urge the material of the blockage into the interior of the second pipe 8. A pulverising device (not shown) is located in the region following the conical portion 12 and is activated so as to pulverise the blockage into a plurality of small particles. These can then be removed along the interior of the second pipe 8 by fluid irrigation or suction. The pulverising means can be in the form of a rapidly rotating drill bit or a grind stone, or an ultrasonic device or a laser. Devices for pulverising blockages are well known in the medical field and need not be described in detail here. Laser light can be guided to the working region (ie. the region where the occluding material is broken into fragments) via optical fibres located within the catheter. Alternatively, total internal reflection at an interface between the or one of the tubes in the catheter and fluid within that tube can be used to guide laser light within the catheter. The laser energy remains shielded from the arterial wall and the laser energy is dissipated in those regions of the fluid experiencing turbulence. This enables the energy to be carried right up to the surface of the occluding material since it is here that turbulent flow occurs.

Figure 3 schematically illustrates a further embodiment of a catheter. A single tube 30 is modified such that its distal end is defined by a relatively thin wall portion 32 which has a plurality of cuts formed therein or portions removed there from in order to separate the thinned wall portion 32 into a plurality of fingers (in a manner similar to that shown in Figures 2, 4 or 5). An inner annular segment 34 is provided towards the base of the fingers 32 thereby defining a substantially annular recess 36 which receives an annular (ring

shaped) catheter balloon. The tube 30 is made from a resiliently deformable material, such as a plastics, and the fingers 32 are naturally biased so as to form smooth continuations of the outer surface of the tube 30. This corresponds to the inoperative condition of the catheter.

In order to move the fingers 32 into an operative condition, gas or liquid is admitted into the catheter balloon 38 thereby causing it to expand. The inward expansion of the catheter balloon 38 is inhibited by the internal walls 34. Thus the force provided by the balloon 38 acts outwardly against the deformable fingers 32 urging them to become splayed and to adopt a configuration similar to that of the fingers 18 and 20 as illustrated in Figure 2 with respect to the first embodiment. A similar arrangement is illustrated in Figure 9, but the balloon 38 is replaced by an axially movable torroidal camming element 80 which can be moved into engagement with profiled portions 82 of the fingers 32 to move them outwardly.

Figures 4 and 5 show embodiments in which the distal portion 40 of an inner tube 41 terminates in three fingers 42, 44 and 46. The material of the tube is processed such that the fingers are naturally biased outwardly, as illustrated in Figures 4 and 5. Thus the fingers of the catheters naturally assume the operating position. An outer sheath 50 surrounds the innermost tube 41 and is longitudinally slidable with respect thereto. Figures 4 and 5 show the tube 41 and the sheath 50 as being relatively short, although it is to be understood that both the proximal ends 52 and 54 of the tube and sheath, respectively, are positioned outside of the patient's body.

In order to insert the catheters, the outer sheath 50 is moved forwardly with respect to the inner tube 41 such that the distal end of the sheath 50 is in contact with the fingers 42, 44 and 46 and urges them inwardly. The distal end of the sheath 50 may extend slightly forward of the fingers 42, 44 and 46 thereby ensuring that they are in their nonoperating state. Once the catheter has been moved to a position such that it is next to the material blocking the artery, the outer most sheath 50 is moved rearwardly with respect to the inner tube 41 (the sheath 50 may be held stationary and the pipe 41 advanced) such that the fingers 42, 44 and 46 extend forwardly of the end of the sheath 50 and expand outwardly,

as shown in Figures 4 and 5, so as to come into contact with the arterial wall. The catheter can then be advanced along the artery in order to cause the material of the blockage to be forced into the interior of the inner tube 41 and towards a pulverising device (not shown).

In order to increase the area of contact with the arterial wall, the fingers may be profiled so as to have an enlarged end 60, as shown in Figure 6. The width H of the enlarged head can be chosen such that the sum of the widths of each finger is greater than the circumference of the inner pipe 41. In such an arrangement, the fingers mutually overlap one another when in the non operative condition, as schematically illustrated in Figure 7. Thus a first side 62 of one finger underlies part of a neighbouring finger, whereas a second side 64 of the one finger overlies the side of another neighbouring finger.

Figure 8 illustrates an advantageous cross sectional profile at an end of a finger. The profile illustrated in Figure 8 can be used with any of the embodiments described herein. The outer surface 70 of the arm 72 is curved such that a sharp end 74 of the arm is held away from the arterial wall 76. Thus the arterial wall abuts a smooth outer portion of the finger 70 thereby avoiding damage to the arterial wall. Meanwhile, the sharp end portion 74 is able to enter into a cleavage zone occurring between the arterial wall 76 and the material blocking the artery (not shown). However the leading edge of the finger can be blunt as the cleaving action can be achieved by peeling as well as cutting.

It is a feature of each of the embodiments that the mechanical device responsible for pulverising the material of the blockage is located within the interior of the device and thereby shielded from coming into contact with the arterial wall. This avoids the risk of puncture or damage to the wall. The catheter is made flexible in order that it can track round the curves occurring within the arteries in order to reach the point of the blockage. In use, the catheter can be pushed along the artery thereby enabling the surgeon to feel when it encounters an obstruction. However force sensors can be built into the distal end of the catheter in order to give an indication of the resistance to movement of the catheter. Furthermore, force sensors, such as strain gauges, can be included within the fingers of the catheter. This enables an increase in strain to be observed when the catheter comes into

contact with occluding material, and equally importantly, a decrease in strain to be observed once the catheter has broken through the occluding material.

Each of the embodiments has been illustrated as being circular in cross section and substantially linear. However it will be appreciated that an elliptical or non-uniform cross-section catheter may be provided for use in partially occluded arteries and similarly a pre-bend may be formed in the catheter for use in removing blockages from curved sections of artery, or for guiding the catheter past junctions or through bifurcations.

It will also be appreciated that the pulverising means can be omitted from the inner pipe 8, or 41, or from the single pipe 30 and in such circumstances the catheter can be advanced around the occluding material in order to grasp and extract it. Under such circumstances, the fingers may be moved to a non operational state so as to grasp the distal portion of the blockage and prevent it from sliding back out of the interior of the catheter.

Figure 10 illustrates a modification of the catheters shown in Figures 4 and 5. The outer sheath 50 is formed with a plurality of openings 90 (which only one is shown) through which an associated finger 92 can extend. A portion 94 of the sheath 50 at the distal end of the opening 90 may be profiled so as to form a camming surface. The chain line 96 represents the central axis of the catheter. The operation of the embodiment shown in Figure 10 is similar to that described with reference to Figures 4 and 5 accept that the finger 92 is arranged to be withdrawn into the window 90 or to extend through the window. The material of the finger 92 does not need to be biased to either one of the operative or non-operative states since the mechanical abutment between the material of the finger 92 and the sheath 50 ensures that the finger is positively moved between the nonoperating and operating states.

Figure 11 shows a variation of the arrangement shown in Figure 10 in which the finger 92 and the inner tube 52 to which it is connected are no longer of a unitary construction and a hinge arrangement 98 is provided to allow pivotal connection between the inner tube 52 and the finger 92.

In a further arrangement, the arms can be formed of a shape memory alloy such that they are movable from the nonoperating to the operating positions upon application of heat to the arms, for example, by ohmic heating.

Although the present invention has been described with reference to catheters, it will be appreciated that it can be used in unblocking a wide variety of fluid flow paths, including sewage pipes. Under such circumstances, the arms form a funnel and the distal ends of the device can be moved forwardly thereby causing the relatively compressible material blocking the pipe to be forced into the inner pipe, the pipe as appropriate and be pulverised or removed.

It is thus possible to provide a simple, reliable and inexpensive device for use both within and outside the medical field.

CLAIMS

1. An apparatus for removing a blockage from an elongate fluid flow path defined by a surface or wall, comprising separating means (4, 6; 32; 42, 44, 46) for separating the material forming the blockage from the surface or wall (76).

2. An apparatus as claimed in claim 1, characterised in that the separating means (4, 6; 32; 42, 44, 46) is arranged to exploit a cleavage plane occurring at or adjacent an interface between the material and the surface or wall (76).

3. An apparatus as claimed in any one of the preceding claims, characterised in that the separating means (4, 6; 32; 42, 44, 46) comprises at least one finger attached at or adjacent a first end of a first flexible member.

4. An apparatus as claimed in claim 3, characterised in that the first flexible member is a hollow pipe (2).

5. An apparatus as claimed in claim 3 or 4, characterised in that the at least one finger is movable between an inoperative position and an operative position such that the at least one finger extends outwardly from the end of the first flexible member (2).

6. An apparatus as claimed in any one of claims 3 to 5, characterised by operating means (12) for urging the or each finger to move between the operative and inoperative positions.

7. An apparatus as claimed in any one of claims 3 to 6, in which a plurality of fingers (4, 6) are resilient biased towards the inoperative position and an operating means (10, 12) is selectively urged into engagement with an inner surface (16) of the fingers (4, 6) causing the distal ends of the fingers to be moved radially outwardly.

8. An apparatus as claimed in claim 7, characterised in that the operating means is a frustro-conical element.

9. An apparatus as claimed in claim 6, characterised by an annular balloon (38) positioned adjacent an inner surface of a plurality of fingers, such that inflation of the balloon causes the fingers to move to the operating position.

10. An apparatus as claimed in claim 6, characterised in that the or each finger (42, 44, 46) is resiliently biased outwardly and an outer sheath (50) surrounds the first flexible member and is moveable longitudinally with respect thereto so as to cover the fingers to move them to an inoperative position and to uncover the fingers thereby allowing them to move to the operative position.

11. An apparatus as claimed in any one of claims 3 to 10 in which the or each fingers is enlarged towards its distal end.

12. An apparatus as claimed in any one of claims 3 to 11, characterised in that the distal ends of the fingers (4, 6; 32; 42, 44, 46) are profiled to turn inwardly so as to reduce damage, in use, to the wall.

13. An apparatus as claimed in any one of claims 3 to 12, characterised in that the distal end of the at least one finger is profiled to have a chisel formed therein so as to assist the cleaving action.

14. An apparatus as claimed in any one of the preceding claims further including vibratory means to cause at least one of longitudinal and rotational motion in order to assist the cleaving action.

15. An apparatus as claimed in any one of the preceding claims, characterised by gas flow passages for allowing gas to be injected along the cleavage plane.

16. An apparatus as claimed in any one of the preceding claims, further comprising removal means for disintegrating or capturing the material of the blockage.

17. An apparatus as claimed in any one of the preceding claims, in which the apparatus includes a fluid flow path such that material from the blockage can be removed by irrigation or suction.

18. An apparatus as claimed in any one of claims 1 to 16, in which material from the blockage is captured inside the first flexible member.

19. A catheter comprising an apparatus as claimed in any one of the preceding claims.

20. A method of removing a blockage for an elongate fluid flow path defined by a surface or a wall, comprising the step of separating the material forming the blockage from the surface or wall and the step of removing or disintegrating the material of the blockage.

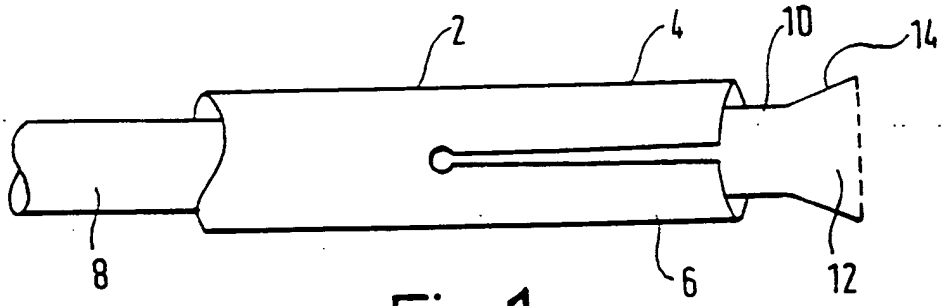

Fig.1.

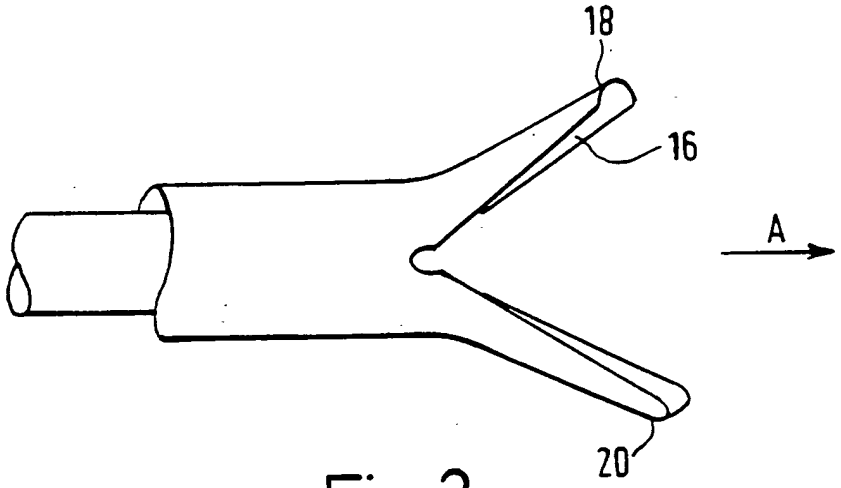

Fig.2.

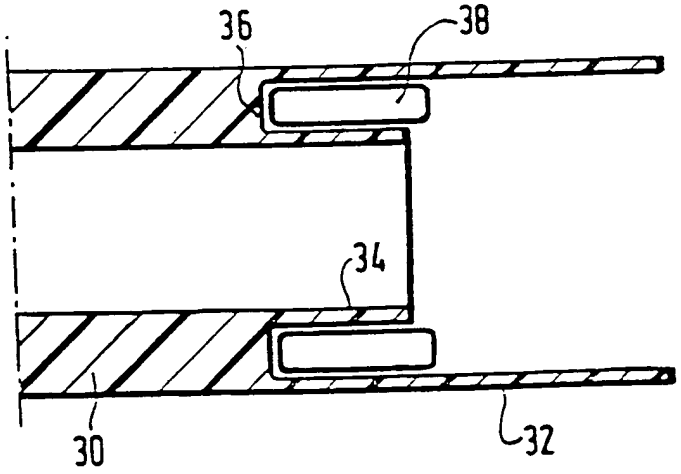

Fig.3.

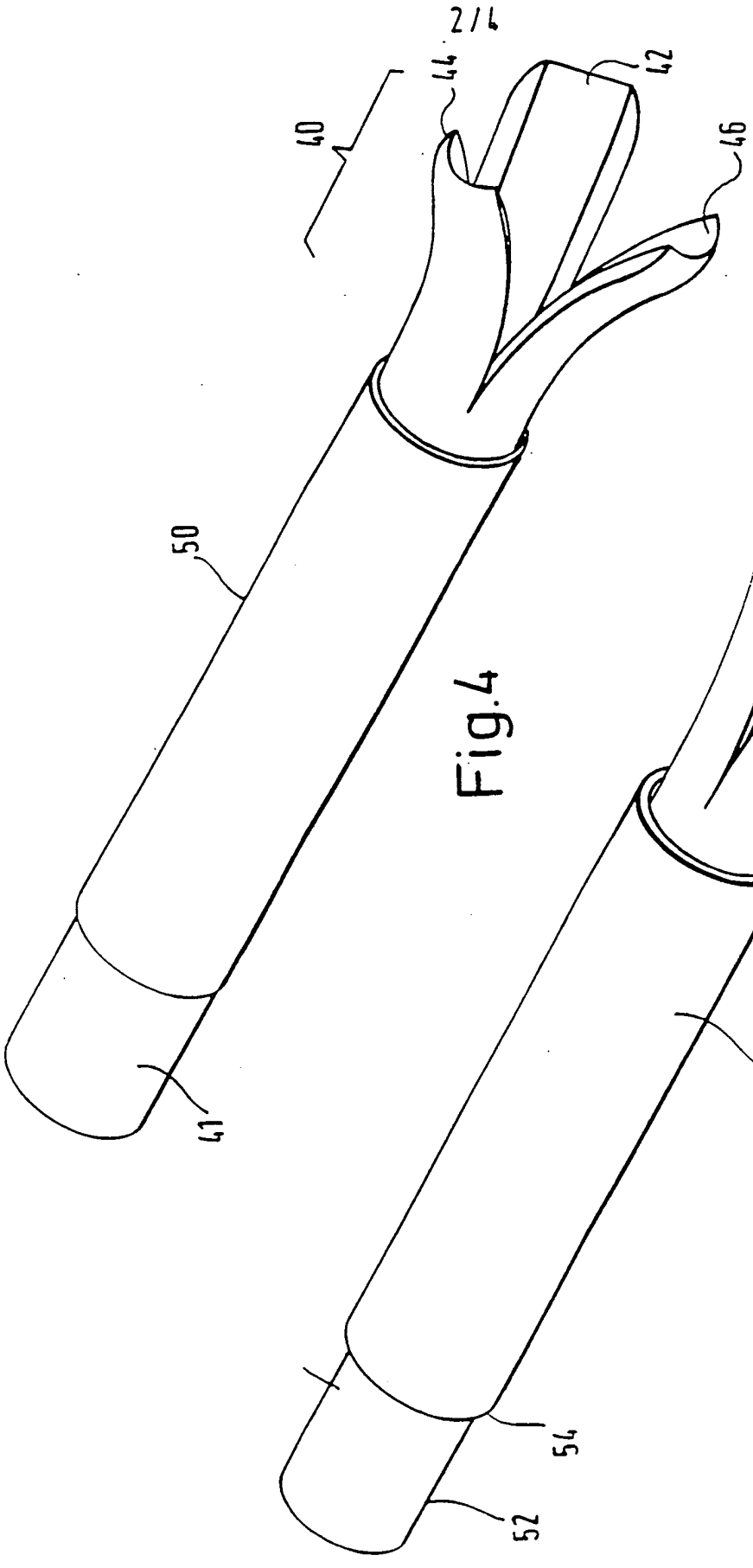

Fig.4

Fig.5.

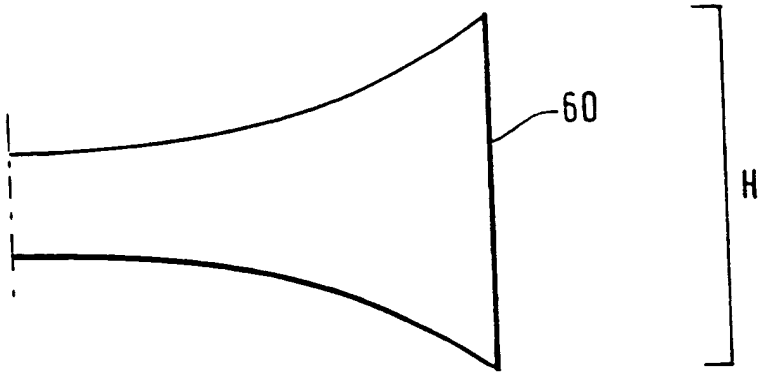

Fig.6.

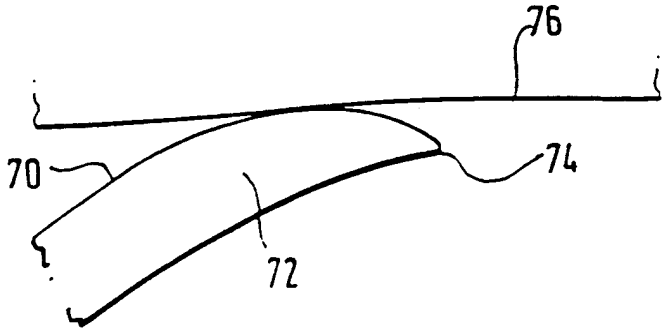

Fig.8.

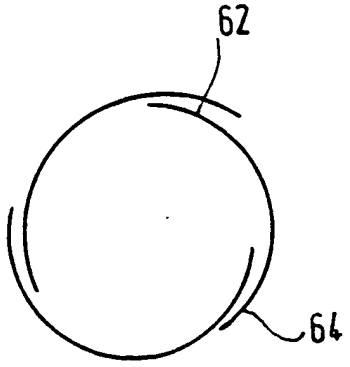

Fig.7

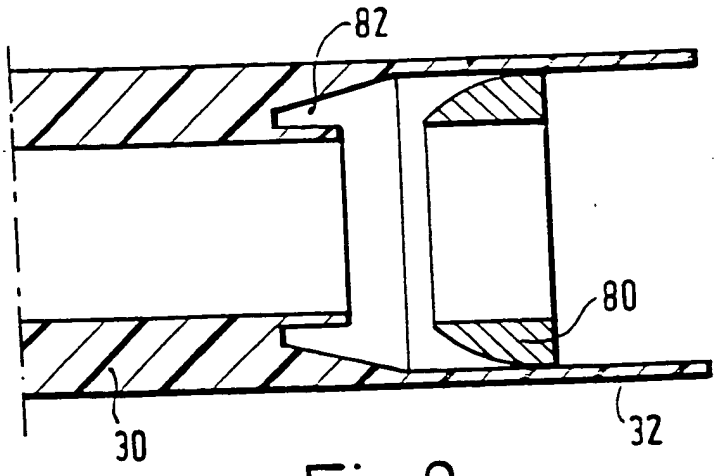

Fig.9.

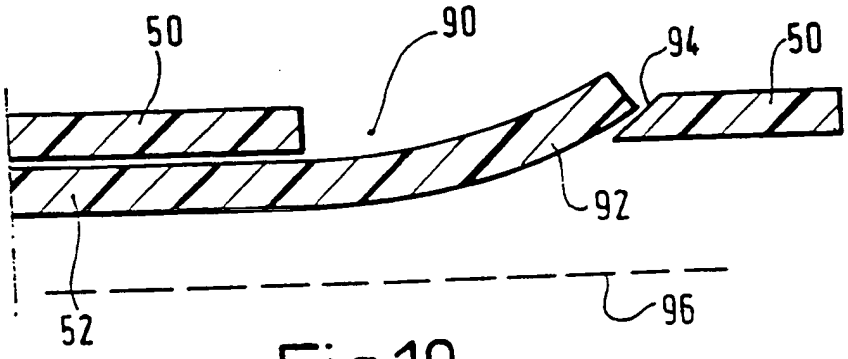

Fig.10.

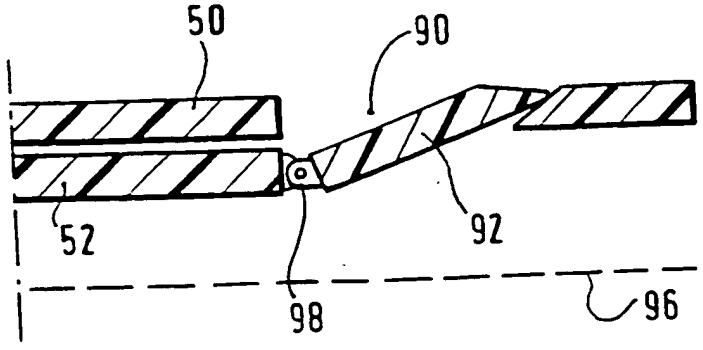

Fig.11

INTERNATIONAL SEARCH REPORT

Inte ɔnal Application No
PCT/GB 98/03380

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 29 33 266 A (HASSE) 27 May 1981 see the whole document	1-6,10, 12,13, 15-19
X	DE 29 45 237 A (LYMBEROPOULOS) 14 May 1981 see the whole document	1-8, 10-12, 18,19
X	US 3 827 437 A (INABA) 6 August 1974 see abstract; figures see column 2, line 25 - column 3, line 29	1-8,15, 18,19
X	DE 19 35 856 A (STENGEL) 4 February 1971 see claims; figures	1-7,12, 13,18,19

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 January 1999	01/02/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

Inte ɔnal Application No
PCT/GB 98/03380

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 748 971 A (BORODULIN ET AL.) 7 June 1988 see abstract; figures	1,2,14, 19
X	DE 15 66 147 A (MONIX ET AL.) 23 July 1970 see figures	1,2
A		9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 98/03380

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

...formation on patent family members

Inter...nal Application No
PCT/GB 98/03380

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 2933266 A	27-05-1981	NONE	
DE 2945237 A	14-05-1981	NONE	
US 3827437 A	06-08-1974	NONE	
DE 1935856 A	04-02-1971	NONE	
US 4748971 A	07-06-1988	DE 3802550 A	11-08-1988
DE 1566147 A	23-07-1970	NONE	